



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

119

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,526	12/29/2003	Andrew Berlin	070702007300	8526

7590 03/21/2007
Raj S. Dave
Morrison & Foerster LLP
Suite 300
1650 Tysons Blvd.
McLean, VA 22102

EXAMINER

LARKIN, DANIEL SEAN

ART UNIT	PAPER NUMBER
2856	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,526	BERLIN ET AL.	
	Examiner	Art Unit	
	Daniel S. Larkin	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 12-15, 20-24, and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-15, 20-24, and 30-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. The indicated allowability of claims 20-24 and 30-37 are withdrawn in view of new arguments. Rejections based on the new arguments follow.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4, 12-15, 20-24, and 30-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to provide one of ordinary skill in the art with a definition of the term "nanocode". The specification discloses, with reference to Figure 3, that a nanocodes 300 includes a reactive molecule, such as a DNA molecule; however, the specification fails to provided any explicit definition of what types of structure can be defined as a nanocodes. Moreover, the specification fails to provide a definition of what types of molecules may be defined as reactive molecules. The specification is very vague as to what nanocodes and reactive molecules are, and what material may or may not be classified as such.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4, 12-15, 20-23, 30, and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0058328 (Chen et al.) in view of US 2003/0033863 (Ashby et al.)

With respect to the limitations of claim 1, the reference to Chan et al. discloses an apparatus for detection, identification, and sequencing of biomolecules, comprising: a probe molecule (410) attached to a nanobarcode (420) comprised of a plurality of carbon nanotubes or fullerenes. The reference further discloses that that the nanobarcodes (420), coded probes, and/or target molecules may be attached to a surface and aligned for analysis by scanning probe microscopy (see paragraph [0023], lines 1-4 and 9-12).

The reference to Chan et al. fails to disclose using a scanning array for simultaneously scanning the molecules. The reference to Ashby et al. discloses an atomic force microscope for use in screening potential interactions between biological molecules comprised of an array of scanning probe tips, as shown in Figure 8. Additionally, the reference to Ashby et al. discloses that the AFM probe array, the individual probes, the surface, or a combination of the above may have independent means for position control (see paragraph [0043], lines 1-3). Providing a scanning array

for simultaneous scanning would have been obvious to one of ordinary skill in the art as means of more quickly detecting and identifying a plurality of molecular samples.

With respect to the limitation of claim 2, the reference to Chan et al. discloses that cantilever torsion of the atomic force microscope will be dependent upon the frictional characteristics of the surface; and the different coded probes can be detected and identified by lateral force microscopy since the frictional characteristics of the coded probes will be different base upon their compositions (see paragraph [0092]).

With respect to the limitation of claim 3, the reference to Chan et al. fails to disclose a scanning array comprising two or more AFM tips. The reference to Ashby et al. discloses an atomic force microscope comprised of an array of two or more scanning probe tips, as shown in Figure 8. Providing a scanning array having multiple scanning tips would have been obvious to one of ordinary skill in the art as means of more quickly detecting and identifying a plurality of molecular samples.

With respect to the limitation of claim 13, the reference to Chan et al. fails to expressly disclose the presence of a substrate holder. The reference to Ashby et al. discloses that means of holding or supporting a substrate/sample is well known in the art as evidenced by Figure 4B. Providing a substrate/sample holder would have been obvious to one of ordinary skill in the art as a means of providing support of the sample as well as a means of moving the sample with respect to the probe array, which in turn help with positioning the probe array with respect to the sample under test.

With respect to the limitation of claim 12, the reference to Chan et al. discloses that the molecules to be detected may include nucleic acid molecules that may be naturally occurring DNA molecules (see paragraph [0030]).

With respect to the limitation of claim 13, the reference to Chan et al. fails to expressly disclose the presence of a substrate holder. The reference to Ashby et al. discloses that means of holding or supporting a substrate/sample is well known in the art as evidenced by Figure 4B. Providing a substrate/sample holder would have been obvious to one of ordinary skill in the art as a means of providing support of the sample as well as a means of moving the sample with respect to the probe array, which in turn help with positioning the probe array with respect to the sample under test.

With respect to the limitation of claim 14, the reference to Chan et al. discloses using a linking group, i.e. molecular assay, as a means to avoid steric hindrance between a nucleotide and a fullerene with hybridization to target nucleic acids.

With respect to the limitations of claim 15, the reference to Chan et al. discloses an apparatus for detection, identification, and sequencing of biomolecules, comprising: a probe molecule (410) attached to a nanobarcode (420) comprised of a plurality of carbon nanotubes or fullerenes. The reference further discloses that that the nanobarcodes (420), coded probes, and/or target molecules may be attached to a surface and aligned for analysis by scanning probe microscopy (see paragraph [0023], lines 1-4 and 9-12).

The reference to Chan et al. fails to expressly disclose moving the scanning probe relative to the substrate/sample. It is the examiner's position, however, that

Art Unit: 2856

movement of the probe with respect to the substrate/sample is very well known in the atomic force/scanning probe microscopy art as a means of properly positioning the sample with respect to the sample. The reference to Chen et al further fails to disclose using a scanning array or a substrate holder. The reference to Ashby et al. discloses an atomic force microscope for use in screening potential interactions between biological molecules comprised of an array of scanning probe tips, as shown in Figure 8.

Providing a scanning array would have been obvious to one of ordinary skill in the art as means of more quickly detecting and identifying a plurality of molecular samples. The reference to Ashby et al. discloses that means of holding or supporting a substrate/sample is well known in the art as evidenced by Figure 4B. Providing a substrate/sample holder would have been obvious to one of ordinary skill in the art as a means of providing support of the sample. Additionally, the reference to Ashby et al. discloses that the AFM probe array, the individual probes, the surface, or a combination of the above may have independent means for position control (see paragraph [0043], lines 1-3). Providing a scanning means for the probe array would have been obvious to one of ordinary skill in the art as a means of providing the apparatus with greater accuracy and precision in moving the probe array with respect to the sample under test.

With respect to the limitations of claim 20, the reference to Chan et al. discloses a method for detection, identification, and sequencing of biomolecules, comprising: providing a probe molecule (410) attached to a nanobarcode (420) comprised of a plurality of carbon nanotubes or fullerenes. The reference further discloses that that the nanobarcodes (420), coded probes, and/or target molecules may be attached to a

surface and aligned for analysis by scanning probe microscopy (see paragraph [0023], lines 1-4 and 9-12).

The reference to Chan et al. fails to disclose using a scanning array to simultaneously scan the molecules. The reference to Ashby et al. discloses an atomic force microscope for use in screening potential interactions between biological molecules comprised of an array of scanning probe tips, as shown in Figure 8. Additionally, the reference to Ashby et al. discloses that the AFM probe array, the individual probes, the surface, or a combination of the above may have independent means for position control (see paragraph [0043], lines 1-3). Providing a scanning array for simultaneous scanning would have been obvious to one of ordinary skill in the art as means of more quickly detecting and identifying a plurality of molecular samples.

With respect to the limitations of claim 21, both the references to Chan et al. and Ashby et al. disclose receiving the scanned information from the probes with an analyzing means; and further providing means for identifying the molecules associated with the specific substrates or nanobarcodes.

With respect to the limitation of claim 22, the reference to Chan et al. discloses that cantilever torsion of the atomic force microscope will be dependent upon the frictional characteristics of the surface; and the different coded probes can be detected and identified by lateral force microscopy since the frictional characteristics of the coded probes will be different base upon their compositions (see paragraph [0092]).

With respect to the limitation of claim 23, the reference to Chan et al. fails to disclose a scanning array comprising two or more AFM tips. The reference to Ashby

Art Unit: 2856

et al. discloses an atomic force microscope comprised of an array of two or more scanning probe tips, as shown in Figure 8. Providing a scanning array having multiple scanning tips would have been obvious to one of ordinary skill in the art as means of more quickly detecting and identifying a plurality of molecular samples.

With respect to the limitation of claim 30, the reference to Chan et al. appears to disclose that all of the materials forming the scanned compositions are comprised of organic materials, such as carbon nanotubes and DNA molecules.

With respect to the limitations of claim 33, and 35, the reference to Chan et al. discloses a method for detection, identification, and sequencing of biomolecules, comprising: providing a probe molecule (410) attached to a nanobarcode (420) comprised of a plurality of carbon nanotubes or fullerenes. The reference further discloses that the nanobarcodes (420), coded probes, and/or target molecules may be attached to a surface and aligned for analysis by scanning probe microscopy (see paragraph [0023], lines 1-4 and 9-12).

The reference to Chan et al. fails to disclose using a scanning array having two or more tips to simultaneously scan the molecules. The reference to Ashby et al. discloses an atomic force microscope for use in screening potential interactions between biological molecules comprised of an array of scanning probe tips, as shown in Figure 8. Additionally, the reference to Ashby et al. discloses that the AFM probe array, the individual probes, the surface, or a combination of the above may have independent means for position control (see paragraph [0043], lines 1-3). Providing a scanning array

for simultaneous scanning would have been obvious to one of ordinary skill in the art as means of more quickly detecting and identifying a plurality of molecular samples.

6. Claims 4, 24, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0058328 (Chen et al.) in view of US 2003/0033863 (Ashby et al.) as applied to claims 3, 23, and 33 above, and further in view of US 5,047,633 (Finlan et al.).

With respect to the limitation of claim 3, the references to Chan et al. and Ashby et al. both fail to expressly recite that the scanning array is a three by three array. The reference to Finlan et al. discloses an apparatus for imaging macromolecules and interactions involving macromolecules, whereby an array of probes (13) is utilized to perform the imaging. One example, as shown in Figure 4, shows a four by four array of scanning probes. It is the examiner's position that one of ordinary skill in the art would have the requisite ability to create a scanning array as large or as small as the operator wishes in order to take advantage of the number of sample needed to be scanned, as well as to more quickly scan a plurality of samples.

With respect to the limitation of claims 24 and 37, the references to Chan et al. and Ashby et al. both fail to expressly recite that the scanning array is a three by three array. The reference to Finlan et al. discloses a method of imaging macromolecules and interactions involving macromolecules, whereby an array of probes (13) is utilized to perform the imaging. One example, as shown in Figure 4, shows a four by four array of scanning probes. It is the examiner's position that one of ordinary skill in the art

Art Unit: 2856

would have the requisite ability to create a scanning array as large or as small as the operator wishes in order to take advantage of the number of sample needed to be scanned, as well as to more quickly scan a plurality of samples.

7. Claims 1-4, 12-15, 20-24, 33, 35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0033863 (Ashby et al.) in view of US 5,047,633 (Finlan et al.).

With respect to the limitations of claims 1 and 20, Ashby et al. disclose an atomic force microscope for use in screening potential interactions between biological molecules comprised of an array of scanning probe tips, as shown in Figure 8; and an analyzer coupled to the scanning array. As to the limitation of providing an array that is "capable of scanning nanocodes", the examiner argues that given that the device of Ashby et al. is an atomic force microscope used to measure on the atomic level, the array of Ashby et al. would inherently have the capability of measuring nanocodes, as it does with measuring small molecules and proteins, among the many other uses available to an atomic force microscope. As to the limitation of "utilizing scanned information to identify molecules", the examiner argues that the microscope of Ashby et al. would have the inherent capability to provide identification; however, the examiner acknowledges that the disclosure fails to expressly disclose that the microscope is used for identification purposes.

Finlan et al. disclose an imaging apparatus and a method of using the apparatus wherein the background of the invention discloses that the invention enables routine

sequencing to be carried out by direct analysis of the molecules under test.

Additionally, the disclosure recites that the invention achieves sufficient resolution to enable individual bases to be structurally distinguished from one another, col. 1, lines 50-56. Given that the bases can be distinguished from one another, the examiner argues that if one knows what one is looking for, then the bases/molecules can also be identified. Providing means for identifying the material being scanned would have been obvious to one of ordinary skill in the art as a means of advancing ones' understanding of the molecules under test.

With respect to the limitation of claim 2, Ashby et al. would again have the inherent capability of measuring friction characteristics.

With respect to the limitations of claim 3, Ashby et al. disclose an atomic force microscope comprised of an array of two or more scanning probe tips, as shown in Figure 8.

With respect to the limitation of claim 4, Ashby et al. fail to expressly recite that the scanning array is a three by three array. Finlan et al. disclose an apparatus for imaging macromolecules and interactions involving macromolecules, whereby an array of probes (13) is utilized to perform the imaging. One example, as shown in Figure 4, shows a four by four array of scanning probes. It is the examiner's position that one of ordinary skill in the art would have the requisite ability to create a scanning array as large or as small as the operator wishes in order to take advantage of the number of sample needed to be scanned, as well as to more quickly scan a plurality of samples.

With respect to the limitation of claim 12, Ashby et al. would again have the

inherent capability of measuring DNA molecules.

With respect to the limitation of claim 13, Ashby et al. appear to disclose means for holding a sample (20).

With respect to the limitation of claim 14, since Ashby et al. would have the inherent capability of scanning nanocodes, the array would also have the inherent capability of measuring molecular assay labels.

With respect to the limitations of claim 15, Ashby et al. disclose an atomic force microscope for use in screening potential interactions between biological molecules comprising: means to support a substrate (20); an array of scanning probe tips, as shown in Figure 8; and an analyzer coupled to the scanning array. As to the limitation of providing an array that is "capable of scanning nanocodes", the examiner argues that given the device of Ashby et al. is an atomic force microscope that is used to measure on the atomic level, the array of Ashby et al. would inherently have the capability of measuring nanocodes, as it does with measuring small molecules and proteins, among the many other uses available to an atomic force microscope. As to the limitation of "utilizing scanned information to identify molecules", the examiner argues that the microscope of Ashby et al. would have the inherent capability to provide identification; however, the examiner acknowledges that the disclosure fails to expressly disclose that the microscope is used for identification purposes.

Finlan et al. disclose an imaging apparatus and a method of using the apparatus wherein the background of the invention discloses that the invention enables routine sequencing to be carried out by direct analysis of the molecules under test.

Additionally, the disclosure recites that the invention achieves sufficient resolution to enable individual bases to be structurally distinguished from one another, col. 1, lines 50-56. Given that the bases can be distinguished from one another, the examiner argues that if one knows what one is looking for, then the bases/molecules can also be identified. Providing means for identifying the material being scanned would have been obvious to one of ordinary skill in the art as a means of advancing ones' understanding of the molecules under test.

Response to Arguments

8. Applicant's arguments filed 28 November 2006 have been fully considered but they are not persuasive.

With respect to Applicants' argument that the references fail to teach an analyzer that is configured to receive simultaneously scanned information and identify molecules associated with the nanocodes, this is correct; however, the examiner argues that apparatus claims are defined by their structure and not their intended uses.

Specifically, it appears that Applicants have taken a generic atomic force microscope and programmed the microscope to detect nanocodes and their associated molecules without any disclosure as to what the changes in the programming have taken place. The specification provides very little detail of the microscope, leading one to conclude that the microscope is a generic, off-the-shelf microscope. Apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. The manner of operating an apparatus does not differentiate an apparatus claim from the

Art Unit: 2856

prior art, if the prior art apparatus teaches all of the structural limitations of the claim (see MPEP § 2114). In this case Ashby and Finlan disclose structure that is capable and may be configured, without undue experimentation, to measure molecules associated with nanocodes.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Larkin whose telephone number is 571-272-2198. The examiner can normally be reached on 8:00 AM - 5:00 PM Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on 571-272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/748,526

Page 15

Art Unit: 2856

Daniel Larkin
AU 2856
16 March 2007



DANIEL S. LARKIN
PRIMARY EXAMINER